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January 28, 2022

VIA ECF & FEDEX

The Honorable Esther Salas, U.S.D.J.
United States District Court
Martin Luther King Jr. Bldg. & U.S. Courthouse
50 Walnut Street
Newark, New Jersey 07102

Re: *Celgene Corporation v. Dr. Reddy's Laboratories, Ltd.., et al.*
Civil Action Nos. 19-15343 (ES)(MAH) (consolidated) & 21-2111 (ES)(MAH)

Dear Judge Salas:

This firm, together with Quinn Emanuel Urquhart & Sullivan and Jones Day, represents Plaintiff Celgene Corporation ("Celgene") in the above-referenced matters.

We are pleased to inform the Court that Celgene and Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. have reached an amicable resolution of these matters. Accordingly, enclosed for Your Honor's consideration are (1) a Consent Judgment directed to U.S. Patent Nos. 8,673,939; 8,735,428; 9,993,467; 10,093,647; 10,093,648; 10,093,649; and 10,555,939 and (2) a Final Judgment Regarding U.S. Patent Nos. 8,198,262 and 8,828,427, which, together, and subject to the Court's approval, would dismiss these matters with prejudice. If the enclosed Judgments meet with the Court's approval, we respectfully request that Your Honor sign them and have them entered on their respective dockets.

Thank you for Your Honor's kind attention to these matters.

Respectfully yours,

Charles M. Lizza

Enclosure

cc: Hon. Michael A. Hammer, U.S.M.J. (via ECF)
All Counsel (via e-mail)

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Attorneys for Plaintiff
Celgene Corporation

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CELGENE CORPORATION, **Plaintiff,** **v.** **DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC.,** **Defendants.**	**Civil Action No. 19-15343 (ES)(MAH) (consolidated)** **Civil Action No. 21-2111 (ES)(MAH)** **(Filed Electronically)**

CONSENT JUDGMENT

Plaintiff Celgene Corporation ("Celgene") and Defendants Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories, Inc. (collectively, "DRL"), the parties in the above-captioned actions, hereby stipulate and consent to entry of judgment and an injunction in these actions as follows:

IT IS this __ day of _____, 2022:

ORDERED, ADJUDGED, AND DECREED as follows:

1. This Court has jurisdiction over the subject matter of the above actions and has personal jurisdiction over the parties for purposes of these actions only, including as set forth below in Paragraph 6 of this Consent Judgment.

2. As used in this Consent Judgment, the term "DRL ANDA Product" shall mean a drug product manufactured, imported, sold, offered for sale, marketed, or distributed pursuant to Abbreviated New Drug Application No. 213234 in or for the United States of America, including its territories, possessions, and the Commonwealth of Puerto Rico.

3. As used in this Consent Judgment, the term "Patents-in-Suit" shall mean U.S. Patent Nos. 8,673,939; 8,735,428; 9,993,467; 10,093,647; 10,093,648; 10,093,649; and 10,555,939.

4. Until expiration of the Patents-in-Suit, DRL, including any of its successors and assigns, is enjoined from infringing the Patents-in-Suit, on its own part or through any third party on its behalf, by making, having made, using, selling, offering to sell, importing, or distributing of the DRL ANDA Product in or for the United States of America, including its territories, possessions, and the Commonwealth of Puerto Rico, unless and to the extent otherwise specifically authorized by Celgene, and is further enjoined from assisting or cooperating with any third parties in connection with any infringement of the Patents-in-Suit by any such third parties in connection with making, having made, using, selling, offering to sell, importing, or distributing of any pomalidomide-containing drug product that references NDA 204026 in or for the United States of America, including its territories, possessions, and the Commonwealth of Puerto Rico, unless and to the extent otherwise specifically authorized by Celgene.

5. Compliance with this Consent Judgment may be enforced by Celgene and its respective successors in interest or assigns.

6. This Court retains jurisdiction to enforce the terms of this Consent Judgment and to enforce and resolve any disputes related thereto.

7. All claims, counterclaims, affirmative defenses, and demands pertaining to the Patents-in-Suit are hereby dismissed with prejudice and without costs, disbursements, or attorneys' fees to any party.

8. Nothing herein prohibits or is intended to prohibit DRL from maintaining any "Paragraph IV Certification" pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) or pursuant to 21 C.F.R. § 314.94(a)(12) with respect to the Patents-in-Suit.

9. Nothing herein prohibits or is intended to prohibit DRL from engaging in any activity permitted under 35 U.S.C. § 271(e)(1).

10. Nothing herein restricts or is intended to restrict the U.S. Food and Drug Administration from approving Abbreviated New Drug Application No. 213234 or the DRL ANDA Product.

_____

Hon. Esther Salas, U.S.D.J.

We hereby consent to the form and entry of this Judgment:

Dated: January 28, 2022

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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CELGENE CORPORATION, **Plaintiff,** **v.** **DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC.,** **Defendants.**	**Civil Action No. 19-15343 (ES)(MAH) (consolidated)** **(Filed Electronically)**

FINAL JUDGMENT REGARDING U.S. PATENT NOS. 8,198,262 AND 8,828,427

WHEREAS, Dr. Reddy's Laboratories, Ltd. and Dr. Reddy's Laboratories Inc. (collectively, "Defendants" or "DRL") submitted Abbreviated New Drug Application ("ANDA") No. 213234 ("DRL's ANDA") for FDA approval of Pomalidomide Capsules 1 mg, 2 mg, 3 mg, and 4 mg ("DRL's ANDA Products"), and submitted Paragraph IV certifications to, among others, U.S. Patent Nos. 8,198,262 (the "'262 patent") and 8,828,427 (the "'427 patent"), and pursuant to 21 U.S.C. § 355(j)(2)(B), notified Celgene Corp. ("Plaintiff" or "Celgene") of those Paragraph IV certifications.

WHEREAS, on July 12, 2019, Plaintiff filed an action for patent infringement against Defendants, alleging that the proposed pomalidomide product described in DRL's ANDA, if

approved, would infringe claims of the ’262 and ’427 patents. *See* Civil Action No. 19–15343 (ECF No. 1).

WHEREAS, on November 12, 2019, Defendants filed an Answer and Counterclaims, denying that the proposed pomalidomide product described in DRL’s ANDA, if approved, would infringe claims of the ’262 and ’427 patents, and alleging counterclaims seeking a declaratory judgment of invalidity, non-infringement, and no injunctive relief as to those patents. *See* Civil Action No. 19–15343 (ECF No. 12).

IT IS HEREBY STIPULATED AND AGREED by Plaintiff and Defendants, subject to the approval of the Court, that the ’427 patent is valid, enforceable, and will not be infringed by DRL’s ANDA Products, and all claims, counterclaims, and affirmative defenses and demands relating to the ’427 patent are hereby DISMISSED WITH PREJUDICE and without costs, disbursement, or attorneys’ fees to any party;

IT IS HEREBY STIPULATED AND AGREED by Plaintiff and Defendants, subject to the approval of the Court, that the ’262 patent is valid, enforceable, entitled to the patent term adjustments and patent term extensions currently existing for that patent, and will be infringed by DRL’s ANDA Products, and all claims, counterclaims, and affirmative defenses and demands relating to the ’262 patent are hereby DISMISSED WITH PREJUDICE and without costs, disbursement, or attorneys’ fees to any party;

THE COURT HEREBY FINDS AND DECLARES that, unless and to the extent specifically authorized by Celgene, Defendants’ making, having made, using, selling, offering to sell, importing, or distributing of DRL’s ANDA Products does and will infringe the asserted claims of the ’262 patent; and

THE COURT HEREBY FINDS AND DECLARES that Defendants' making, having made, using, selling, offering to sell, importing, or distributing of DRL's ANDA Products does not and will not infringe any claim of the '427 patent; and

FINAL JUDGMENT of validity, enforceability, and infringement of the '262 patent as well as the propriety and enforceability of the patent term adjustments and patent term extensions currently existing for that patent, is hereby entered in favor of Plaintiff. Until expiration of the '262 patent, DRL, including any of its successors and assigns, is enjoined from infringing the '262 patent on its own part or through any third party on its behalf, by making, having made, using, selling, offering to sell, importing, or distributing DRL's ANDA Products in or for the United States of America, including its territories, possessions, and the Commonwealth of Puerto Rico, and is further enjoined from assisting or cooperating with any third parties in connection with any infringement of the '262 patent by any such third parties in connection with making, having made, using, selling, offering to sell, importing, or distributing of any pomalidomide-containing drug product that references New Drug Application No. 204026 in or for the United States of America, including its territories, possessions, and the Commonwealth of Puerto Rico, unless and to the extent specifically authorized by Celgene.

FINAL JUDGMENT of validity and enforceability of the '427 patent is hereby entered in favor of Plaintiff.

FINAL JUDGMENT of noninfringement of the '427 patent is hereby entered in favor of Defendants.

This Court retains jurisdiction to enforce the terms of this Final Judgment and to enforce and resolve any disputes related thereto.

Compliance with this Judgment may be enforced by Celgene and its respective successors in interest or assigns.

The Parties hereby waive their right to any appeal of this Final Judgment.

_____

Hon. Esther Salas, U.S.D.J.

We hereby consent to the form and entry of this Judgment:

Dated: January 28, 2022

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